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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,342		Richard Rex Denton	2458-4042US5	1812

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GENAISSANCE PHARMACEUTICALS
5 SCIENCE PARK
NEW HAVEN, CT 06511

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,342

Applicant(s)

DENTON, RICHARD REX

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-68, 110-119 and 161-170 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 59-68, 110-113, 115-118 and 161-170 is/are rejected.
- 7) ☐ Claim(s) 114 and 119 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/12/03 (1 page)</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment filed 12/21/02 cancels claims 1-58, 69-109, 120-160, and 171-183. Claims 59-68, 110-119, and 161-170 are under consideration by the examiner.

Priority

The petition granted 9/16/02 converts the instant application from an application filed under 35 USC 371 to an application filed under 35 USC 111(a). The instant application has been given a filing date of 12/21/01. As PCT/US00/17540 designated the United States, the instant application is considered to be a continuation of PCT/US00/17540, filed 6/26/00, which claims priority to provisional application 60/141,521, filed 6/25/99.

The first page of the specification should be amended to reflect applicant's priority claim and the relationship between the various applications.

Inventorship

In view of the papers filed 11/4/03, the inventorship in this nonprovisional application has been changed by the deletion of inventors R. Rex Denton, Guablerto Ruano, J. Claiborne Stephens, Chuanbo Xu. The inventors are Richard S. Judson and Andreas K. Windemuth.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt and PTO PALM data to reflect the inventorship as corrected.

Claim Objections

Claims 114 and 119 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to claims in the alternative. See MPEP § 608.01(n). Accordingly, the claims 114 and 119 have not been further treated on the merits.

Information Disclosure Statement

An information disclosure statement was submitted 6/12/03. The Form PTO-1449 in the file had only one page. The documents listed on this page have been considered and the form initialed. It appears that there should have been five more pages as the upper right hand corner says "Page 1 of 6." These pages do not appear to be present in the file.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 59-68 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 59-68 are non-statutory as the methods merely manipulate data and do not produce a tangible, concrete, and useful result.

Claim Rejections - 35 USC § 112

Claims 59-68, 110-113, 115-118, and 161-170 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 59-68 are directed to methods of determining polymorphic sites or sub-haplotypes that correlate with a clinical response or outcome of interest.

Claims 110-118 are directed to computer-usable media having computer-readable program code stored thereon. The computer-readable code essentially executes the methods of claims 59-68.

Claims 161-170 are directed to computers programmed to determine polymorphic sites or subhaplotypes that correlate with a clinical response or outcome of interest, or other phenotype. The computers are programmed essentially to execute the methods of claims 59-68.

The claims require haplotype information and clinical response or outcome data from a cohort of subjects as input. Each individual SNP in the haplotype is analyzed. For example, step (c) requires saving for further processing particular individual SNPs or haplotypes. The specification and claims do not make clear what information is being saved or how it is saved for further processing. Is a record containing the haplotype information, particular SNP information, clinical response information marked? Is a new database created with particular information? Clearly, to accomplish the goals of the method more information must be retained than that required by the claim. See also step (f). It appears that the claims as written are incomplete with respect to exactly what is input, what is processed and how, what specifically is saved, and what information is output. For example, in claim 59 all possible pair-wise combinations are generated according to the criteria set forth; however, they aren't necessarily saved or output in a usable form by the method. Note that the correlation and cut-off values are not specified such that the methods and products embrace generating information that is in not meaningful to those of ordinary skill in the art (no correlation, negative correlation, low cut-off value).

For example, suppose the cohort had 2 subjects. Suppose each subject had a unique haplotype and each subject had different clinical response or outcome data. For example, the

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information for subject A was had a migraine, took Advil, pain was ameliorated and the information for subject B was terminal cancer, radiation therapy unsuccessful. The specification does not teach how to practice the method with this information nor what meaningful information might be expected to be extracted. The claims don't speak to size or composition of the cohort such that statistically valid results are produced, comparison of like information, and so forth.

Finally, the specification discloses no databases readily available to the public containing the information required by the claims. It is considered to be undue experimentation to produce such a database as it would require one of ordinary skill in the art to exercise inventive skill and judgment in determining what information to include and exclude and in what form to compile the information decided upon for statistical analysis.

Claims 59-68, 110-113, 115-118, and 161-170 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 recites "(clinical outcome values)." It is unclear whether this parenthetical phrase is a specific limitation of the claims. See also at least claims 110, 112, 161, and 163.

Claim 63 recites "complex subhaplotypes." It is unclear what the metes and bounds of this phrase are. It cannot be determined from which subhaplotypes would be considered complex and therefore excluded from further processing. See also at least claim 68.

It appears that claims 59, 64, 110, 112, 115, 117, 161, 163, 166, and 168 should have "and" inserted between parts (g) and (h).

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Claim 66 appears to contain a typographical error, "fi3st." It is assumed that "first" was intended.

Claims 110-113, 115-118, and 161-170 are unclear as to whether each portion of computer-readable program code (i.e. (a) through (h)) are a sections of a single program, separate programs, or something else. The claims don't make clear any relationship between the program code of the subparts. For example, it is unclear if the code must be executed sequentially, in a particular order, in any order, or that output from one part of code is used as input to another part of the code.

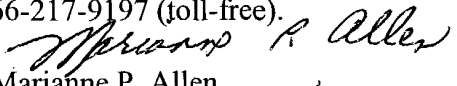
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner
Art Unit 1631

3/22/04

mpa